## REMARKS/ARGUMENTS

The Examiner's attention to the present application is noted with appreciation.

**Section 102 Rejection.** Claims 1-7 and 12-16 are rejected under 35 U.S.C. § 102(b) as being anticipated by Laufer et al. (U.S. Patent No. 5,730,136). This ground of rejection is respectfully traversed.

At the outset, it is noted that Laufer et al. is directed to an entirely different purpose than the Applicant's invention. Laufer et al. provides "a test system and method for evaluating the efficiency of the venous pump in leg muscles and for identifying incompetent venous valves." See Abstract, lines 1 -3; see also col. 1, ll. 7-11; col. 3, line 59 bridging col. 4, line 58; and col. 9, line 18 bridging col. 11, line 18. By contrast, Applicant's invention is directed to an apparatus for "enhancing return blood flow in a lower extremity to prevent thrombosis in a human body." See claim 1, lines 1 - 2; see also page 1, lines 11 - 12; page 3, line 2 bridging page 5, line 2; and elsewhere through the application. Applicant appreciates that for section 102(b) purposes, whether a cited prior art references that is asserted to anticipate is "analogous" or "teaches away" is not relevant. See MPEP 2131.05. Nonetheless, in conducting the anticipation or novelty analysis it is important to understand the scope and import of the prior art reference to determine whether it truly anticipates.

It is well-established that a claim is "anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Thus it is required that the "identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). See also MPEP 3131 et seq.

Applicant's invention, as set forth in claim 1, is to an apparatus. This apparatus requires the following elements:

> an impedance component disposed at the proximal end of the lower extremity that when activated impedes return venous blood flow by compressing a vein, thereby increasing venous fill in the lower extremity; and

a compression component disposed at the distal end of the lower extremity that is activated in response to deactivation of said impedance component and compresses at least a portion of the lower extremity such that return venous blood flow is enhanced.

Thus claim 1 requires that compression component have two features: that it be "activated in response to deactivation of said impedance component" and further than upon activation it then "compresses at least a portion of the lower extremity such that return venous blood flood is enhanced."

As discussed below, the cited Laufer et al. reference fails to disclose the above two features of the Applicant's invention as set forth in claim 1. Simply put, the Laufer et al. reference fails to disclose the elements as claimed, and fails to disclose the "identical invention" as claimed.

Laufer et al. discloses a series of "inflatable bands or bladders" **30** (see FIG. 2) that are arrayed around the patient's lower and upper leg. (See col. 5, ll. 39-42) While the nomenclature utilized it not necessarily determinative, each of "bands or bladders" **30** is identical, and there is no teaching in Laufer et al. that one "band or bladder" is an "impedance component" and another is a "compression component" within the meaning of Applicant's claim 1. In fact, each band or bladder **30** of Laufer et al. is identical, and each acts as a "pneumatically activated tourniquet" (col. 5, ll. 39-40).

The operation of the device of Laufer et al. is described in detail. In all modes of operation the "bladders or cuffs **30** in the legging **18** are inflated from the ankle or foot to the upper thigh in sequence so as to cause restrictions which milks the blood out of the legs." (Col. 9, ll. 32-35; see also col. 9, ll. 45-48). In testing for individual incompetent valves, Laufer et al. starts with "the lowest or first cuff (closest to the ankle)." Col. 9, ll. 56. Then the "second" or next lowest cuff is inflated, and so on up the leg. Col. 9, line 66 bridging col. 10, l. 28. In an additional diagnostic test, for incompetence of deep veins, the same methodology is employed (starting at the lowest or first cuff), with initial full compression, and deflation to superficial vein compression only. Col. 10, ll. 30-39. However, in all embodiments described the only mode of operation, and the only function for the "controller **12**" or the "control circuit **50**" is to sequentially "activate the bladders or cuffs **30** ... from the ankle or foot to the upper thigh in sequence." (Id.)

Thus the apparatus of Laufer et al. does not anticipate because it does not disclose "a compression component disposed at the distal end of the lower extremity that is activated in response to deactivation of said impedance component and compresses at least a portion of the lower extremity such that return venous blood flow is enhanced." There is no express or implied teaching that an upper component (at the proximal end of leg, i.e., the upper thigh) can be configured such that deactivation of this upper component (the "impedance component") causes activation of a distal compression component (i.e., the ankle or foot) "in response deactivation of said impedance component."

It might be argued that one, having knowledge of Applicant's invention, which is for a therapeutic purpose and not a diagnostic purpose, could alter the programming of the apparatus of Laufer et al. to function analogous to Applicant's invention as set forth in claim 1. However, that is not the test. This would require alteration to the apparatus of Laufer et al., because Laufer et al. neither explicitly nor implicitly teaches a device with the interrelationship and arrangement of elements as claimed in Applicant's claim 1. It is not explicit because no where does Laufer et al. disclose that a foot or ankle compression component is activated (i.e., compression initiated) in response to deactivation of a previously activated impedance component on the upper thigh. It is not implicit because no where does Laufer et al. suggest that the device might be used for therapeutic purposes, but rather solely discloses diagnostic testing, and in the diagnostic testing solely discloses sequential activation from the foot to the thigh, without any prior activation of an upper thigh band or cuff, and without any temporal or causal relationship between activation of a lower band or cuff and deactivation of a previously activated upper thigh band or cuff. Because the apparatus of Laufer et al. must necessarily be changed by altering the interrelationship of the components, the mode of operation and the programming or other control means, it does not anticipate.

It is further noted that Laufer et al. in no way discloses the limitations of certain of the dependent claims. Specifically, claim 7 requires that "impedance component is activated until blood volume in the lower extremity is maximized, and said compression component is activated in response to deactivation of said impedance component." There is nothing even remotely analogous to this in Laufer et al. Claim 12

provides "a control unit to control the activation and deactivation of said impedance component and of said compression component." While Laufer et al. discloses a "control unit", it does not disclose one that controls as provided in claim 1, i.e., where the compression component is activated in response to deactivation of the impedance component. Similarly, claim 13, dependent on claim 12, provides that the "control unit coordinates the deactivation of said impedance component and activation of said compression component in response to feedback from said sensor unit." Laufer et al. does not disclose that a control unit may be design or made to function as described in claim 13.

Claim 15 is amended consonant with the foregoing argument, by adding a provision thereto that the controller provides the function of "sequentially activating the means for impeding venous flow, deactivating the means for impeding venous flow, and activating the means for compressing at least a portion of the distal end of the lower extremity in response to deactivation of means for impeding venous flow, whereby return venous blood flow is enhanced." This is not taught by Laufer et al.

**Section 103 Rejection.** Claims 8-11 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Laufer et al. in view of Laufer et al. While the preamble does not so state (Detailed Action at page 3, first full paragraph), Applicant understands that the rejection is also intended to apply to method claims 17-20, and responds accordingly. This ground of rejection is respectfully traversed.

As discussed above in detail, Laufer et al. is directed to a method and apparatus for diagnosis of the functional status of venous valves. There is no teaching or suggestion in Laufer et al. that either the method or the apparatus may be employed in therapy, specifically "enhancing return blood flow in a lower extremity to prevent thrombosis in a human body." While both Laufer et al. and Applicant's invention relate to the "medical arts" broadly considered, there is no suggestion or argument why it would be obvious to take a diagnostic device and adapt it to a therapeutic purpose, particularly where, as here, the mode of operation of the diagnostic method is distinctly different than that of the therapeutic method.

As discussed above in detail, no where does Laufer et al. teach or suggest that, as stated in claim 17 hereof, a method for a therapeutic purpose by "impeding the venous blood flow at the proximal end of the lower extremity for a defined period of time thereby increasing venous fill in the lower extremity; and

compressing a portion of the distal end of the lower extremity, such compression being initiated in a relationship to release of impedance of the venous blood flow at the proximal end of the lower extremity." To the contrary, Laufer et al. neither teaches nor suggests any therapeutic method. Further, Laufer et al. never teaches nor suggests first impeding venous blood flow at "the proximal end of the lower extremity" to increase venous fill in the lower leg, and then compressing the foot or ankle "in a relationship to release of impedance of the venous blood flow." That someone with knowledge of Applicant's invention might be able to reprogram the device of Laufer et al. to accomplish this method is irrelevant; to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974); MPEP 2143.03. The limitations of Applicant's claim 17 are neither taught nor suggested by Laufer et al.

Similarly, with respect to claims 8-11, because Laufer et al. never teaches nor suggests a therapeutic method, but simply and solely describes a device and method for diagnosis, it would not be obvious to employ pressure settings relevant to therapy, but which are without any asserted or established relevance to a diagnostic method or device.

**Consideration of Previously Filed Information Disclosure Statement.** An information disclosure statement was filed with the application, including two pages on Form 1449A, two pages on Form 1449B, and numerous prior art articles. The information disclosure statement and references are shown on Private PAIR. It is respectfully requested that the Examiner show such references as considered, and return an initialed copy of the relevant forms with the next Office Action.

In view of the above amendments and remarks, it is respectfully submitted that all grounds of rejection and objection have been avoided and/or traversed. It is believed that the case is now in condition for allowance and same is respectfully requested.

If any issues remain, or if the Examiner believes that prosecution of this application might be expedited by discussion of the issues, the Examiner is cordially invited to telephone the undersigned attorney for Applicant at the telephone number listed below.

Also being filed herewith is a Petition for Extension of Time to June 13, 2005, with the appropriate fee. Authorization is given to charge payment of any additional fees required, or credit any overpayment, to Deposit Acct. 13-4213. A duplicate of this paper is enclosed for accounting purposes.

Respectfully submitted,

By: _____

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